K090569

APR 1 0 2009

# 510(k) SUMMARY

# VIDAS® CA 125 II Assay

## A. Submitter Information

| | |
|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Sandra Perreand |
| Phone Number: | 314-731-8594 |
| Fax Number: | 314-731-8689 |
| Date of Preparation: | October 8, 2008 |

## B. Device Name

| | |
|---|---|
| Trade Name: | VIDAS® CA 125 II Assay |
| Common Name: | CA 125 |
| Classification Name: | Test, Epithelial Ovarian Tumor-Associated Antigen (CA125) |

## C. Predicate Device Name

| | |
|---|---|
| Trade Name: | TOSOH Medical, Inc. ST AIA Pack CA 125 Enzyme Immunoassay |

## D. Device Description

VIDAS® CA 125 II is an automated quantitative test for use on the VIDAS instruments, for the measurement of CA 125 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 125 II is indicated for the serial measurement of OC 125 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with Stage IV (metastatic) ovarian cancer for disease progression or response to therapy. The VIDAS CA 125 II assay can also be used as an aid in the early detection of recurrence in previously treated Stage II and III ovarian cancer patients.

CA 125 II is a registered trademark from Fujirebio Diagnostics Inc. (formerly named Centocor Diagnostics of Pennsylvania, Inc.)

The assay principle combines a two-step immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR), a pipette tip-like device, serves as the solid phase as well as the pipetting device for the assay. It is coated with mouse monoclonal M 11 antibodies. The other assay reagents are ready-to-use and pre-dispensed in the sealed reagent strips (STRs). The individual kit components are described in detail on the following pages.

All of the assay steps are performed automatically by the instrument. The reaction medium is cycled in and out of the SPR several times. This operation enables the monoclonal M11 antibody fixed onto the interior wall of the SPR to capture the reactive

antigenic determinants present in the sample. Unbound components are eliminated during the washing steps. Alkaline phosphatase labeled mouse monoclonal OC 125 antibody (conjugate) is then incubated in the SPR where it binds with the OC 125 reactive antigenic determinant. Unbound conjugate is then eliminated during the washing steps.

During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone) the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of OC 125 reactive antigenic determinants present in the sample.

At the end of the assay, results are automatically calculated by the instrument in relation to the calibration curve stored in memory, and then printed out.

## E. Intended Use

VIDAS® CA 125 II is an automated quantitative test for use on the VIDAS instruments, for the measurement of OC 125 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 125 II is indicated for the serial measurement of OC 125 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with ovarian cancer for disease progression or response to therapy. The VIDAS CA 125 II assay can also be used as an aid in the detection of recurrence in previously treated ovarian cancer patients.

## F. Technological Characteristics Summary

A general comparison of the similarities and differences of the VIDAS CA 125 II assay to the predicate device is presented in the table below.

| Item | VIDAS® CA 125 II Assay | TOSOH ST AIA-PACK CA 125 (K023891) |
|---|---|---|
| **General Comparison** | | |
| **Intended Use** | VIDAS® CA 125 II is an automated quantitative test for use on the VIDAS instruments, for the measurement of OC 125 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 125 II is indicated for the serial measurement of OC 125 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with ovarian cancer for disease progression or response to therapy. The VIDAS CA 125 II assay can also be used as an aid in the detection of recurrence in previously treated ovarian cancer patients. | ST AIA-PACK CA 125 is designed for IN VITRO DIAGNOSTIC USE ONLY for the quantitative measurement of CA 125 in human serum on specific TOSOH AIA System analyzers. ST AIA-PACK CA 125 is to be used as an aid in monitoring response to therapy for patients with epithelial ovarian cancer. Serial testing for patient CA 125 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer. |
| **Specimen** | Serum | Serum |

| Item | VIDAS® CA 125 II Assay | TOSOH ST AIA-PACK CA 125 (K023891) |
|---|---|---|
| **Analyte** | CA 125 | CA 125 |
| **Antibody** | mouse monoclonal anti-CA 125 | mouse monoclonal anti-CA 125 |
| **Assay Principle** | Two antibody "sandwich" binding of CA 125 antigen. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound | Two antibody "sandwich" binding of CA 125. One antibody is bound to a solid phase and the second antibody is in liquid form and is labeled with fluorescent compound |
| **Automated** | Yes | Yes |
| **Assay Technique** | Enzyme-linked fluorescent assay (ELFA) | Two-site immunoenzymometric assay |
| **Sample Volume** | 200 µL | 100 µL |
| **Traceability/ Standardization** | Master curve for each kit lot and each calibrator lot are traceable to working standards established by bioMérieux, Inc. and value assigned by the Fujirebio Diagnostics, Inc. radioimmunoassay method | Each calibrator lot are traceable to internal reference standards |
| **Measurement range** | 4.00 – 600.00 U/mL | 2.0 – 1,000 U/mL |

## G. Performance Data

A summary of some of the non-clinical and clinical test results is presented in the tables below.

### Precision:

Three serum samples were tested in duplicate in 40 different runs (2 runs per day over 20 sequential days) with 2 reagent lots using one instrument at each of three sites (N = 480). The between-site precision, between-lot precision, between-recalibration precision, between-day precision, between-run precision, repeatability (within-run precision) and total precision (within-run, between-run, between-day, between-recalibration, between-lot and between-site) were calculated using a modified protocol, which was written based on the recommendations of CLSI® EP5-A2:

| Source | N | Pool A (389 U/mL) | Pool B (75.3 U /mL) | Pool C (18.9 U /mL) |
|---|---|---|---|---|
| | | CV (%) | CV (%) | CV (%) |
| Between-site | 480 | 4.15 | 2.13 | 2.43 |
| Between-lot | 480 | 1.01 | 0.00 | 0.79 |
| Between-recalibration | 480 | 1.87 | 2.26 | 1.96 |
| Between-day | 480 | 0.00 | 1.08 | 0.74 |
| Between-run | 480 | 0.99 | 2.00 | 1.79 |
| Within-run | 480 | 3.40 | 3.50 | 3.35 |
| Total | 480 | 5.85 | 5.20 | 5.03 |

### Measurement range

The measurement range of the VIDAS CA 125 II kit is: 4-600 U/mL.

### Analytical detection limit

Based on a modification of CLSI® document EP17-A , LoB, LoD and LoQ detection limit results are estimated to be less than 4 U/mL.

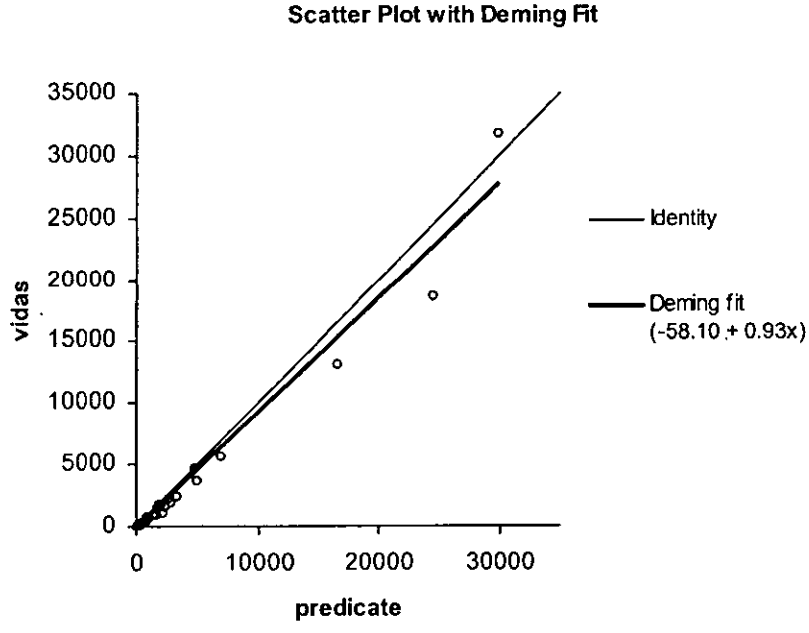
### Hook effect

No hook effect was found up to OC 125 reactive antigenic determinant concentrations of 200,000 U/mL.

### Comparison with other test methods

One serum sample randomly chosen from each of the 77 women with ovarian cancer tested for the monitoring of the disease status (77 samples) and for the expected values (133 samples) using the VIDAS® CA 125 II (Y) assay were compared with another commercially available CA 125 II assay (X). The results obtained are presented below (Deming). The equation represents the relationship between the two techniques.

n = 210
Y = 0.93X – 58.10
95% Confidence interval for the intercept: -169.15 to 52.95
95% Confidence interval for the slope: 0.61 to 1.25
Range of samples: 4.0 – 31801 U/mL (VIDAS); 2.0 – 29940 U/mL (another commercially available assay)



## H. Conclusion

The VIDAS® CA 125 II Assay is substantially equivalent to the Tosoh Medical, Inc. ST AIA Pack CA 125 Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 10 2009

BioMérieux, Inc.
c/o Ms. Sandra L. Perreand
Senior Director, North American Regulatory Affairs
595 Anglum Rd
Hazelwood, MO 63042

Re: k080561
Trade/Device Name: VIDAS® CA 125 II™
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LTK
Dated: April 07, 2009
Received: April 08, 2009

Dear Ms. Perreand,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

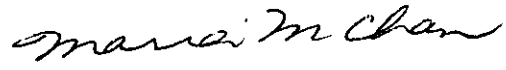
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K080561

Device Name: VIDAS® CA 125 II

Indication For Use:

VIDAS® CA 125 II is an automated quantitative test for use on the VIDAS instruments, for the measurement of OC 125 reactive antigenic determinants in human serum using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS CA 125 II is indicated for the serial measurement of OC 125 reactive antigenic determinants as an aid in the monitoring of patients previously diagnosed with ovarian cancer for disease progression or response to therapy. The VIDAS CA 125 II assay can also be used as an aid in the detection of recurrence in previously treated ovarian cancer patients.

Prescription Use ___X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K080561